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| EXAMINER | |
|---|---|
| HA, JULIE | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/539,434 | GERHARDT ET AL. | |
| | Examiner | Art Unit | |
| | JULIE HA | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-10,12,13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12,13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/08, 5/13/08, 6/30/08, 7/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Amendment to Non-final rejection filed on April 28, 2008 is acknowledged. Claims 2, 11 and 14 have been cancelled. Claims 1, 2-10, 12-13 and 15-17 are pending in this application and examined on the merits in this office action.

### *Withdrawn Objections*

1. Objections to claims 2, 8 and 11 are hereby withdrawn due to Applicant's cancellation of claims 2 and 11.

### *Maintained Rejection*

### *35 U.S.C. 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3-10, 12-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reimer et al (WO 01/37850) in view of O'Callaghan et al (WO 93/04593).

6. Reimer et al teach a method of treatment of diabetes comprising administering an effective amount of a composition comprising sweet or acid whey proteins or hydrolysates (page 1, lines 11-14). The sweet or acid whey taught by Reimer et al comprises whey protein hydrolysates and minor proteins that remain intact (page 8, lines 4-8) and is capable of stimulating the release of active GLP-1 in the NCI-H716 intestinal cell line (page 15, lin3s 11-23). The composition taught by Reimer et al may be in the form of fermented milk, yogurt, cheese, confectionary bar, breakfast cereal flakes or bars, drinks, milk powders, soy-based products or nutritional supplements for clinical nutritional supplements (page 10, lines 29-33). Reimer et al do not teach that the average molecular weight of the whey protein hydrolysates is in the range of 1000-12000 Daltons, that the whey protein hydrolysates comprises hydrolysates of β-

lactoglobulins, α-lactalbumin or a mixture thereof, or that the degree of hydrolysis is in the range of 0.1% to 80% by weight.

7. O'Callaghan et al teach hypoallergenic whey protein hydrolysates for use in infant formula (page 6, line 28) prepared by proteolytic treatment (page 6, line 33). The whey protein hydrolysate has an average molecular weight of 1854.7 Daltons (the weighted average molecular weight based on the molecular weight distribution reported in Table 4). The whey protein hydrolysates taught by O'Callaghan et al comprises lactalbumin hydrolysates (Table 4). Assuming a molecular weight of 16000 Daltons for α-lactalbumin, the degree of hydrolysis of the whey protein in this composition is 11% (Table 4).

8. It would have been obvious to use the hypoallergenic whey protein hydrolysates taught by O'Callaghan et al in place of the sweet or acid whey protein in the method of treating diabetes as taught by Reimer et al. In particular, it would have been obvious to orally administer this composition to subjects suffering from Type 2 diabetes or glucose intolerance and in doing so, improve or prevent a decline in mental performance, provide a sustained feeling of energy and maintain or provide a feeling of well-being during the post-prandial period in the same subjects. The skilled artisan would have been motivated to substitute the hypoallergenic whey protein hydrolysates taught by O'Callaghan et al for the sweet or acid whey protein in the method of treating diabetes taught by Reimer et al based on the teaching of Reimer et al that the sweet or acid whey can be further hydrolyzed, for example to prepare a hypoallergenic whey protein hydrolysate (page 8, lines 16-18). The skilled artisan would have been motivated to

target Type 2 diabetic patients with impaired glucose tolerance (diabetics) based on the teachings of Reimer et al. Specifically, Reimer et al discuss that Type 2 diabetic suffer from insulin resistance and that diabetics in general are aided by receiving controlled amounts of insulin (page 1, lines 31-36). Reimer et al then comment that insulin injection is not safe, convenient or acceptable to the patient as oral administration (page 2, lines 1-6). Reimer et al go on to say that compositions that induce the release of GLP-1, a potent insulin secretagogue (page 2, line 10), can be used to improve glucose homeostasis in vivo. Finally, Reimer et al teach that sweet or acid whey, which can be administered orally, is capable of stimulating the release of active GLP-1 in the NCI-H716 intestinal cell line (page 15, lines 11-23). There would have been a reasonable expectation that the substitution of the whey protein hydrolysates taught by O'Callaghan et al for that of Reimer et al would be successful given that the whey protein hydrolysates taught by O'Callaghan et al is also designed for oral administration to humans.

9. The combination of the Reimer et al and O'Callaghan et al references satisfy all of the limitations of claim 1: an edible composition comprising whey protein hydrolysates with an average molecular weight between 1000-12000 Daltons is orally administered to subject (any subject). Because the composition and patient population (anybody, including subjects suffering from Type 2 diabetes) are same to the claimed invention, the effects of improving or preventing a decline in mental performance, providing a sustained feeling of energy and maintaining or providing a feeling of well-being during the post-prandial period will result. With respect to claim 8, the whey protein hydrolysate

comprises α-lactalbumin. With respect to claim 3, the whey protein hydrolysate has a degree of hydrolysis in the range of 1% to 20%. With respect to claims 5-9, 12 and 13, the compositions may be in the form of a powder, liquid concentrate or ready-to-drink beverage, fermented milk, yogurt, cheese, confectionary bar, breakfast cereal flakes or bars, drinks, milk powders, soy-based products or nutritional supplements for clinical nutritional supplements and are therefore designed a meal replacement products to be used as part of a diet plan to maintain glucose homeostasis (Reimer et al, page 3, line 4). Regarding claims 4 and 15, Reimer et al teach that compositions comprise at least 0.01% sweet or acid whey by weight which differs from the claimed range of 0.1% to 80%, preferably 1% to 30%. It would have been obvious to the skilled artisan to optimize the concentration of whey protein hydrolysates in the composition in order to effectively induce GLP-1 secretion and control glucose homeostasis in the subject. With respect to claims 16 and 17, O'Callaghan et al teach compositions comprise a pH of 6.42% (Table 3) and maintaining pH at 8.0 (page 15, lines 30-32) and the degree of hydrolysis of the whey protein in this composition is 11% (Table 4). It would have been obvious to the skilled artisan to optimize the concentration of whey protein hydrolysates in the composition in order to effectively induce GLP-1 secretion and control glucose homeostasis in the subject. Section 2144.05 of the MPEP states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the

prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

10. Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

***Response to Applicant's Arguments***

11. Applicant argues that "there is no incentive for a person of average skill in the art to combine the teachings of Reimer with those of O'Callaghan. Reimer teaches to treat type II diabetes with the help of milk protein hydrolysates. Reimer teaches that caseinoglycomacropeptide (CGMP) is largely responsible for the GLP-1 inducing effect of certain milk protein hydrolysates." Applicant further argues that "O'Callaghan relates to infant formulae and special dietetic foodstuffs that contain a hypoallergenic whey protein hydrolysate...The Office points to no data or suggestions in O'Callaghan which imply that the hypoallergenic whey protein hydrolysates described therein are capable of inducing GLP-1 release." Applicant further argues that "knowing that the peptide part of CFMP, the essential component in the milk protein hydrolysates of Reimer, has a molecular weight of 8,000 Dalton, but that the molecular weight of the glycosylated molecule can range from 25, 000 to 30,000 Daltons, a skilled person would expect the hypoallergenic whey hydrolysates of O'Callaghan to be largely ineffective in the method taught by Reimer. The molecular weight distributions of the hypoallergenic whey protein hydrolysates depicted in the Tables 2, 4, 6, 8 and 10 contain only a minor fraction of material having a molecular weight in excess of 5,000 Daltons." Applicant further argues

that "present claim 1 recites that the whey protein hydrolysates contains 30-45% of material having a molecular weight of at least 10,000 Daltons. However, the hypoallergenic whey protein hydrolysates described in Tables 2, 4, 6, 8 and 10 contain 2.3-11.2 wt% of material having a molecular weight of at least 5,000 Daltons."

12. Applicant's arguments have been fully considered but have not been found persuasive because the prior arts combined teaches the present invention. Reimer et al teach that milk protein hydrolysate can induce the release of GLP-1 and it can be used to improve glucose homeostasis in vivo (page 3, lines 1-2). Furthermore, Reimer et al teach that the term "milk protein hydrolysates" is taken to mean milk proteins that have been subjected to any sort of hydrolysis (page 6, lines 18-19), and "sweet whey" and "acid whey" are also considered to be possible milk protein hydrolysates, because they are the product of enzymatic or acid hydrolysis of milk proteins (page 6, lines 24-26). Reimer also indicates that sweet and acid whey stimulate the release of active GLP-1 in the NCI-H716 intestinal cell line (See results section), not just CGMP as indicated by Applicant. Thus, this implies that any sweet and acid whey stimulates the release of active GLP-1. Furthermore, Reimer et al teach that "it is also clear to the skilled person, that protein hydrolysate present in sweet or acid whey can be further hydrolyzed, for example to prepare a hypoallergenic whey protein hydrolysate...such a hydrolysate may then be used as a liquid or it may be dried and incorporated in numerous food products" (page 8, lines 16-22).

Furthermore, O'Callaghan et al teach that modification of food proteins by enzymatic hydrolysis is well documented and can be used to reduce the allergenicity of

bovine milk proteins for inclusion in hypoallergenic baby formulae and special dietetic foods (page 2, lines 30-33). Furthermore, O'Callaghan et al teach that Asselin et al (1989) demonstrated that hydrolysis of whey proteins with pepsin followed by a-chymotrypsin was the most efficient combination of enzymes to reduce allergenicity of α-lactalbumin and β-lactoglobulin (page 3, lines 2-5). O'Callaghan et al teaches that enzymatic hydrolysis of whey protein leads to reduced allergenicity of α-lactalbumin and β-lactoglobulin. Whey protein as a whole has these proteins. Further, O'Callaghan teaches a process for the production of a hypoallergenic whey protein hydrolysate comprising hydrolyzing a substrate with a proteolytic enzyme, thermally inactivating the enzyme and microfiltering the product of hydrolysis (page 6, lines 3-6). The reference further teaches that the invention provides a hypoallergenic whey protein hydrolysates comprising peptide which range in molecular weight from free amino acids to 50,000 Daltons...may also comprise lactose (page 6, lines 22-24). Since the claims are drawn to an active method comprising the step of orally administering to the subject an edible composition an effective amount of a whey protein hydrolysates, and the patient population can be anybody, this implies that the edible composition can be an infant formula or special dietetic composition, as taught by O'Callaghan et al. The combination of references teaches all of the limitations (whey protein hydrolysates being orally administered) of the instant application. In regards to Applicant's argument that Tables 2, 4, 6, 8 and 10 (of O'Callaghan reference) contain only a minor fraction of material having a molecular weight in excess of 5,000 Daltons, O'Callaghan teaches different ranges of whey protein hydrolysates profile. Therefore, it would have been obvious to

one of ordinary skill in the art to optimize the concentrations of the whey protein profile to optimize the GLP-1 secretion and control glucose homeostasis in the subject. Controlling glucose homeostasis (blood/sugar regulation) will regulate the availability of glucose to maximize its energy (ATP) making potential in the body. Therefore, the whey protein hydrolysates taught by Reimer et al and O'Callaghan et al must have all of the characteristics and functionality as the claimed whey protein hydrolysate. Therefore, the rejection is maintained.

***Obvious Double Patenting***

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

14. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

15. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 3-10, 12-13 and 15-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-

5, 7-9, 1 and 19 of copending Application No. 10/519657 (US PG Pub 2005/0238694 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because if one practiced the claimed invention of instant application, one would necessarily lead to the claimed invention of the co-pending application and vice versa.

17. The instant claims are drawn to a method of improving or preventing decline in mental performance, providing a sustained feeling of energy or maintaining or providing a feeling of well being during the post-prandial period in a subject comprising the step of orally administering to the subject by means of an edible composition an effective amount of a whey protein hydrolysates.

18. The claims of copending application are drawn to the method of use of a whey protein hydrolysates in an edible composition, the whey protein hydrolysates being able to induce the cellular release of glucagons-like peptides and cholecystokinins, wherein the whey protein hydrolysates induces an enhanced feeling of satiety (claims 1, 3-10 and 12-13) and a method of treating obesity or being overweight in/or a subject, comprising administering to the subject an edible composition comprising an effective amount of whey protein hydrolysate, the whey protein hydrolysate being able to induce the cellular release of glucagon-like peptides and cholecystokinins (claim 19).

19. If one of ordinary skill in the art practiced the claimed invention of instant application, one would necessarily achieve the claimed invention of the copending application, and vice versa, because the same active agent is being administered to the same subject (anybody) according to the same active method steps.

20. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Applicant's Arguments***

21. Applicant indicates that Applicant is willing to file a terminal disclaimer upon indication of allowable subject matter.

22. Until a properly executed terminal disclaimer is filed and approved by the Office, Obviousness Double Patenting rejection is maintained.

***Conclusion***

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). No claims are allowed.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. H./
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654